REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1-10 are pending. The amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. The scope of claim 5 is not changed because the amendment merely reformats the Markush language in more convention form. Claim 1 is amended by incorporating the limitations of original claim 4.

Remarks regarding 35 U.S.C. § 102:

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 1-3, 5, 7 and 8 stand rejected under 35 U.S.C. § 102 as allegedly anticipated by U.S. Patent 4,935,359 (referred to herein as "Yin") and Sugisawa et al. (Biosci. Biotechnol. Biochem., 2005 69:659-662, referred to herein as "Sugisawa"). Applicants traverse.

Claim 1, as amended, is directed to a process for vitamin C production from L-sorbosone by contacting cells belonging to the genus Ketogulonicigenium with a medium containing L-sorbosone and isolating the produced vitamin C from the reaction mixture. The amount of vitamin C which are produced with different Ketogulonicigenium strains are depicted in Table 1 (Specification, page 6).

The claims, as amended, are not anticipated by Yin, inter alia, because Yin (1) uses a different starting material, (2) produces a different product, and (3) uses a different mixture of organisms. First, Yin does not disclose the starting material of the claimed process. The amended claims are directed to the use of L-sorbosone as a starting material. Yin is silent on the use of L-sorbosone as a starting material. Second, Yin does not disclose the use of the claimed organisms. The amended claims are directed to the use of microorganisms belonging to the genus Ketogulonicigenium. Yin describes the usage of a mixed culture of G. oxydans and B. megaterium (i.e., different

strains as in claim 1, even if G. oxydans DSM 4025 has been later reclassified as K. vulgare), wherein G. oxydans DSM 4025 is mentioned as a preferred Gluconobacter strain. As the Office Action has admitted on page 6, first paragraph, Yin does not use the same strain of bacterium as that of the claimed invention. Third, Yin does not disclose the production of the claimed end product by the claimed process. The amended claims are directed to the production of vitamin C in a process involving the use of a microorganism belonging to the genus Ketogulonicigenium. In contrast, Yin is directed to a process for the production of 2-KGA, an end product which is different from Applicants' claimed vitamin C, from a substrate such as L-sorbose or D-sorbitol (a different substrate than the claimed substrate). Yin only mention the production of vitamin C by the Reichstein process (Yin, col. 1, lines 9-12) via esterification, enolization, and lactonization (Yin, col. 3, lines 63-65) which is not the subject of the pending claims. The claims as presented are novel and not anticipated by Yin, inter alia, because Yin uses a different starting material and uses a different mixture of organisms to produce a different end product. Since Yin does not disclose all the limitations of the pending claims, it cannot anticipate the pending claims.

Sugisawa is not a valid prior art for anticipation. The instant application is the U.S. national phase of international application PCT/EP2005/000622 filed January 22, 2005 which designated the U.S. and further claims the benefit of EP 04002074.5 dated January 30, 2004. Sugisawa was published on March 23, 2005 which is **after** the instant applications' priority dates of January 22, 2005 and January 30, 2004. (See attached printout from Biosci. Biotechnol. Biochem.) For this reason, the claimed invention is not anticipated by Sugisawa.

Furthermore, Yin's reaction conditions do not inherently produce vitamin C as the Examiner has suggested. First, Yin's reaction conditions are not exactly the same as that of Sugisawa and there is no reason to expect that the same processes would occur absent identical reaction conditions. Second, Yin is directed to a reaction condition significantly different from Sugisawa. Yin's condition involves a specific mixture of two organisms Gluconobacter oxydans and Bacillus megaterium. The two organism are essential to Yin's disclosure. Applicants note that Yin neither disclose or claim

processes involving only one organism. The fact that these two organisms are needed indicates that they have an effect on the behavior of each other and on the resulting product. In fact, Yin states in column 2, lines 54 to 59, that:

> "The quantitative ratio of Bacillus colonies to Gluconobacter colonies at the beginning of the fermentation process is not critical. This ratio may e.g. be in the range between 1:10 and 1:300 (Bacillus: Gluconobacter). This ratio adjusts itself automatically, in the course of the fermentation process, to an optimal value.

Since the bacteria population self adjusts and clearly have an effect on each other, there is no basis to assume that the two organism culture of Yin is identical to or would provide the same chemical reaction as that of Sugisawa or Applicants' claimed invention. Third, Yin's stated in its specification that its ultimate goal is to produce vitamin C and Yin's claimed process produces 2-KGA (2-keto-L-gulonic acid), an intermediate (Yin, col. 1, lines 9-13). Yin further recommends the Reichstein method for conversion of 2-KGA into vitamin C. The Reichstein method has a number of disadvantages for commercial applications such as the use of large quantities of toxic reagents/solvents and the involvement of a number of complex reaction steps. If Yin's process inherently produced vitamin C, there would be no need for Yin to recommend the Reichstein process with its various disadvantages and there would be a great incentive for Yin to claim the production of vitamin C instead of claiming the production of an intermediate. For these reasons, there is simply no bases to assume that Yin's process inherently produced vitamin C.

For the reasons stated above, the cited document does not anticipate the claimed invention because it does not disclose all limitations of independent claim 1. Moreover, claims 5-10 depend from independent claim 1 and are also not anticipated by the document because the limitations of claim 1 are incorporated in claims depending therefrom. See *In re McCarn*, 101 USPQ 411, 413 (C.C.P.A. 1954). The rejection is moot with respect to claims 2-4 because these claims are canceled.

Withdrawal of the Section 102 rejection is requested because the cited document fails to disclose all limitations of the claimed invention.

Remarks regarding 35 U.S.C. § 103:

A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. *In re Kahn*, 78 USPQ2d 1329, 1334 (Fed. Cir. 2006) citing *Graham v. John Deere*, 148 USPQ 459 (1966). The *Graham* analysis needs to be made explicitly. *KSR v. Teleflex*, 82 USPQ2d 1385, 1396 (2007). It requires findings of fact and a rational basis for combining the prior art disclosures to produce the claimed invention. See id. ("Often, it will be necessary for a court to look to interrelated teachings of multiple patents . . . and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue"). The use of hindsight reasoning is impermissible. See id. at 1397 ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning"). Thus, a prima facie case of obviousness requires "some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct." *Kahn* at 1335; see *KSR* at 1396. A claim directed to a combination of prior art elements "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." Id.

Claims 1-3 and 5-8 stand rejected under 35 U.S.C. § 103 as allegedly obvious in view of U.S. Patent 4,935,359 (referred to herein as "Yin"), U.S. Patent 6,316,231 (referred to herein as "Stoddard"), Sugisawa et al. (Biosci. Biotechnol. Biochem., 2005 69:659-662, referred to herein as "Sugisawa"), Urbance et al. (Int. J. of Systematic and Evolutionary Microbioloby, 2001, 51:1059-1070, referred to herein as "Urbance") and a printout from NCBI Taximony browser for Ketogulonicigenium vulgare (referred to herein as "NCBI"). Applicants traverse.

As discussed above, the disclosure of Yin, even in combination with Sugisawa, fails to disclose the claimed invention. The addition of Stoddard, Urbance, and NCBI does not cure this defect. As correctly stated by the Examiner, Yin mentions that 2-KGA (2-keto-L-gulonic acid) may be converted to vitamin C (L-ascorbic acid). However, Yin

does not render the instant claims obvious because Yin only discloses the conversion of 2-KGA into vitamin C by three additional chemical steps - "esterification, followed by enolization and lactonization." See, Yin, col. 3, lines 63-65. These steps of conversion taught by Yin at least involves the addition of base or acid to the reaction mixture. Yin's method does not inherently produce vitamin C and, in fact, teaches away from Applicants' claimed method because (1) Yin never discloses the presence of vitamin C in any of his processes – except after esterification, enolization and lactonization and (2) by teaching that a chemical process of esterification, enolization and lactonization is needed for conversion of 2-KGA into vitamin C, Yin shows that his method is incapable of producing vitamin C via a biological method. Actually, Yin does not teach the conversion of L-sorbosone into vitamin C via the intermediate 2-KGA at all.

The failure of Yin and Sugisawa to disclose the claimed invention is not remedied by the attempt to combine their disclosure with Stoddard, Urbance, and NCBI. Stoddard teaches the use of Ketogulonicigenium strains for the production of 2-KGA wherein the substrate is selected from, for example, L-sorbose or D-sorbitol. There is no suggestion on the use of a microorganism together with L-sorbosone in order to obtain vitamin C as a direct conversion product.

Urbance and NCBI were cited by the Examiner to show reclassification of G. oxydans DSM 4052. The reclassification does not alter the substance of Applicants' comments above.

Claims 1-10 stand rejected under 35 U.S.C. § 103 as allegedly obvious in view of Yin, Stoddard, Sugisawa, Urbance, NCBI and Asakura et al. (Biosci. Biotechnol. Biochem. 1999 63:46-53. Applicants traverse.

As discussed above, the combination of Yin, Stoddard, Sugisawa, Urbance, and NCBI does not render obvious Applicants' claimed invention. Further, Applicants are in agreement with the Examiner who stated that a combination of Yin, Stoddard, Sugisawa, Urbance, and NCBI does not teach the production of vitamin C from L-sorbosone (Office Action, page 9, lines 1-2). In this rejection, the Examiner has added Asakura because Asakura allegedly provides the missing teaching (i.e., the production of vitamin C from L-sorbosone.) Applicants disagree.

Asakura is directed to the isolation and characterization of an enzyme which is able to catalyze the conversion of, for example, L-sorbose with or without L-sorbosone into 2-KGA. The publication does not make any reference to the production of vitamin C from L-sorbosone. In contrast, as shown in Figure 6 and discussed on page 52, right column, the enzyme has a strong 2-KGA producing capability. Asakura does not teach and does not render obvious the claimed invention which is directed to a process involving L-sorbosone and a microorganism of Ketogulonicigenium for the production of vitamin C as claimed.

Therefore, the combination of Yin, Stoddard, Sugisawa, Urbance, NCBI and Asakura does not render obvious the claimed invention as represented by claim 1. Moreover, claims depending from independent claim 1 are also not rendered obvious by the cited documents because all limitations of the independent claims are incorporated in their dependent claims. M.P.E.P. § 2143.03 citing *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

Withdrawal of the Section 103 rejections is requested because the claims would not have been obvious to one of ordinarily skill in the art when this invention was made.

Conclusion

Having fully responded to the pending Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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